

NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM

MEMORANDUM OF UNDERSTANDING

Model: May 5, 1993

Memorandum of Understanding on Collaboration Between the Office of Prevention, Pesticides, and Toxic Substances of the U.S. Environmental Protection Agency (EPA) and [ORGANIZATION'S NAME].

I. Purpose

The purpose of this Memorandum of Understanding (MOU) is to establish a process by which the Environmental Protection Agency (EPA) Office of Pollution Prevention and Toxics (OPPT) formally recognizes [ORGANIZATION'S NAME] as a laboratory accrediting organization working in cooperation with the EPA National Lead Laboratory Accreditation Program (NLLAP). Laboratories which are accredited by [ORGANIZATION'S NAME] for the analysis of lead in the matrices of paint chips, dust, and/or soil, will be recognized by the NLLAP as being capable of performing adequate analyses for lead in the matrix or matrices for which it has been accredited.

II. Background

In an effort to establish a national accreditation program for laboratories conducting analyses for lead in paint, dust and soil matrices associated with the evaluation and control of lead-based paint hazards, EPA/OPPT will draw upon the capabilities of private and public laboratory accrediting organizations. In order to assure to the public that a laboratory accrediting organization is capable of performing an adequate assessment of participating laboratories, EPA will establish this MOU with accrediting organizations in recognition of their capability to perform adequate laboratory assessments meeting the conditions and requirements stated below.

The following definitions are specific to this MOU:

Accreditation--A formal recognition that a laboratory is competent to perform analyses of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. Competence will be based on successful performance in both a proficiency testing program and systems audit (inclusive of an on-site assessment) by programs/organizations recognized by NLLAP.

Assessor--One who performs a systematic evaluation of a laboratory on behalf of a laboratory accreditation organization.

Environmental Lead Proficiency Analytical Testing Program (ELPAT Program)--The proficiency testing program recognized by the NLLAP. Participation on a quarterly basis in this program is mandatory for all laboratories seeking accreditation by an NLLAP recognized laboratory accrediting organization.

EPA National Lead Laboratory Accreditation Program (NLLAP)--A voluntary laboratory accreditation program with EPA OPPT oversight, which recognizes private sector and public laboratory accreditation organizations capable of performing adequate laboratory assessments as a part of their accreditation program of laboratories requesting accreditation for the analysis of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards. Laboratories accredited by an NLLAP recognized accrediting organization will be recognized by EPA under NLLAP.

Laboratory--A facility that is requesting accreditation for the analyses of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards.

Laboratory Accreditation Organization (accreditation organization)--An organization which seeks recognition from the EPA NLLAP as being capable of performing adequate laboratory assessments for laboratories requesting accreditation for the analysis of lead in paint chips, dust and/or soil samples associated with the evaluation and control of lead-based paint hazards.

III. Authority

Under Title X, Section 405(b) of the Residential Lead-Based Paint Hazard Reduction Act of 1992, EPA is required to establish protocols, criteria, and minimum performance standards for laboratory analysis of lead in paint films, soil, and dust. It also requires EPA to determine if effective voluntary laboratory accreditation programs are in place and operating on a nationwide basis. If such programs are not operating effectively within two years (October 28, 1994), EPA is to establish a laboratory certification program for all laboratories which demonstrate an ability to accurately test paint films, soil and dust samples for lead.

IV. Substance of Agreement

EPA NLLAP recognition of a laboratory accrediting organization by the signing of this MOU, will depend upon a satisfactory evaluation of the laboratory accrediting organization's operation. This evaluation will be done through the EPA review of the documents identified below for submission. The general requirements for laboratory accreditation organizations participating in the NLLAP are stated in ISO Guide 58, "Calibration and Testing Laboratory Accreditation Systems-General Requirements for Operation and Recognition" of the International Organization for Standardization and International Electrochemical Commission (ISO/IEC). Accreditation organizations must state their specific program requirements addressing the general requirements stated in ISO Guide 58, inclusive of the specific requirements stated below. A copy of ISO Guide 58 can be obtained from the American National Standards Institute (ANSI). Their Customer Service Department can be reached by calling (212) 642-4900.

[ORGANIZATION'S NAME] agrees to the following:

1. Submit to EPA/OPPT for review, their organizational quality manual (QM) and related documents which describe the quality system currently in place. Guidance on the general requirements which laboratory accreditation organizations are to address in the submitted QM can be found in ISO Guide 58.

The QM and/or related organizational documents must state all requirements (see item 3 below) for laboratory's seeking accreditation. The QM and/or related documents must specify organizational procedures for the removal of a laboratory's accreditation based on the laboratory's failure to maintain the conditions specified in the accreditation requirements. In the event that a laboratory loses its accreditation status, EPA NLLAP officials must be notified in writing within five working days of the action by the laboratory accreditation organization.

EPA/OPPT is to be notified in writing within 30 days after a decision has been made to implement major changes in organizational policies or management of the accreditation organization which could effect the NLLAP.

2. Establish and implement a training program and continuing education program for assessors using the most current revision, including amendments of the EPA developed curriculum guidance document entitled "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations For Assessor Training Programs--Revision 1.0" (EPA document No. 747-R-92-005) or their own

curricula which addresses the areas covered in the EPA guidance document. In cases where the laboratory accreditation organization develops their own training curricula, the curricula must be reviewed by EPA in advance of the signing of this MOU by EPA. Requirements for qualifications for beginning assessor candidates and experienced assessors are to meet those stated in the EPA curriculum guidance document mentioned above. The accrediting organization has the option to utilize the assessor training program of another accrediting organization recognized by the NLLAP. Copies of the document "Pb-Based Paint Laboratory Accreditation: Curricula Recommendations For Assessor Training Programs--Revision 1.0" can be obtained from the National Lead Information Center Clearinghouse by calling 1-800-424-LEAD.

3. Perform a systems audit on applicant laboratories inclusive of an on-site assessment applying their general and environmental program requirements which must be inclusive of the minimum requirements stated in the most recent revision of the NLLAP "Laboratory Quality System Requirements." A copy of the most recent revision of the NLLAP "Laboratory Quality System Requirements" is provided in Appendix A.

All NLLAP assessors are required to fill out a checklist for each on-site assessment. The checklist utilized may be the example provided in the EPA publication "Pb- Based Paint Laboratory Accreditation: Curriculum Recommendations For Assessor Training Programs-- Revision 1.0", or one developed which addresses the areas covered by the example. The laboratory checklists shall be kept on file for 10 years by the laboratory accreditation organization as a part of the accreditation documentation.

4. Require that all laboratories applying for accreditation perform successfully (rated proficient or "P" by the National Institute for Occupational Safety and Health (NIOSH)) in the Environmental Lead Proficiency Analytical Testing Program (ELPAT) as administered by American Industrial Hygiene Association (AIHA) and NIOSH. Laboratories must participate in the ELPAT program on a quarterly basis as new rounds of proficiency testing samples are made available. The accrediting organization is responsible to make arrangements with NIOSH in order to secure the ELPAT data of participating laboratories.

5. Reevaluate laboratories accredited by it for lead analysis at a minimum of once every three years. This reevaluation would include a systems audit inclusive of an on-site visit. Laboratories which have been cited as having performed inadequately based on customer complaints, or poor performance in the ELPAT program are to be subject to more frequent reevaluation.

6. Upon approval of an accredited laboratory, provide to designated personnel of the EPA NLLAP accreditation information including the date the accreditation is effective, the accreditation expiration date and the matrices which the laboratory is accredited for. The accreditation organization shall also provide a continual update of the laboratory's accreditation standing over time as reassessments and performance evaluation reviews are conducted as well as any other information relevant to supporting an accreditation decision. Within 45 days after the accreditation of a laboratory, EPA NLLAP personnel are to be provided by the accrediting organization with the date the accreditation is in effect and the expiration date of the accreditation. A list of all current accredited laboratories is to be supplied to EPA NLLAP personnel at least once every three months.
7. Maintain records for a period of ten years of the terms of accreditation of each accredited laboratory including all complaints received from customers of the accredited laboratory. This information is to be available upon request to EPA.
8. Not to delegate fully or partially the responsibility of laboratory assessment to another organization which is not recognized under the NLLAP.
9. Not to accredit laboratories under NLLAP which practice the sub-contracting of routine sample analyses for which the laboratory is recognized under NLLAP, unless the laboratory under consideration for the sub-contract is also recognized under the NLLAP for the same analyses.
10. Participate in meetings with EPA at least once every two years in an effort to help provide a formal evaluation of NLLAP.

The Office of Pollution Prevention and Toxics (OPPT) as the overseeing EPA Office of the NLLAP agrees to :

1. Recognizes [ORGANIZATION'S NAME] as a laboratory accrediting organization for the NLLAP based on the requirements and conditions set forth in this MOU. Laboratories accredited by [ORGANIZATION'S NAME] for the NLLAP shall be recognized by EPA as capable of analyzing for lead in the specified matrix of paint, and/or dust, and/or soil samples during the period of their accreditation. A list of laboratories which have been accredited will be made available to the public by EPA.
2. Provide guidance on NLLAP requirements, indicating in writing to accrediting organizations when such requirements have been amended.

3. Conduct evaluations of NLLAP accrediting organizations at least once every three years or more frequently if needed, based on complaints concerning the organizations performance or significant changes in the organization's program. These evaluations will be the responsibility of OPPT's Chemical Management Division (CMD), Technical Programs Branch. Evaluation criteria will be based on the requirements stated in Section IV above.

4. Reserves the right to accompany NLLAP recognized accrediting organization assessors during an on-site visit in order to observe the performance of the NLLAP recognized accrediting organization's assessor in the field.

V. Management & Implementation

The NLLAP is managed as a part of the OPPT's Chemical Management Division's (CMD) Lead Program. The responsibility for implementing and support of the program lies with CMD personnel. It is the responsibility of CMD's Technical Programs Branch (TPB), to forward recommendations to the Director of OPPT as to the signing of this MOU based on evaluation of the quality manual and related documents, including assessor training curricula, of candidate laboratory accreditation organizations seeking initial recognition or to maintain recognition by EPA as a part of the NLLAP.

Inquiries concerning the NLLAP can be addressed to the attention of John Scalera/NLLAP at the following address:

Chemical Management Division/Technical Programs Branch (TS-798)
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
401 M Street, S.W.
Washington, D.C. 20460

Laboratory accrediting organizations recognized by EPA under the NLLAP are responsible for implementing their lead laboratory accreditation program including the training of their assessors. Representatives of each accrediting organization in the NLLAP program would be responsible for participating in meetings at least once every two years in an effort to refine and improve the NLLAP.

VI. Funding

Accrediting organizations recognized by the EPA NLLAP are responsible for the training of their assessors, the costs involved in obtaining ELPAT data for the laboratories of concern, and all other costs incurred in running their program to meet the

requirements set forth in this MOU. It is the option of the accrediting organization to recover these costs by assessing fees to participating laboratories for their services.

VII. Revision or Termination

This MOU shall enter into force upon signature, and shall remain in force for 3 years, at which time a reevaluation of the NLLAP recognized laboratory accrediting organization's program will be done by OPPT. EPA reserves the right to terminate this MOU before the 3 years period in the event OPPT finds the accrediting organization in noncompliance with the conditions agreed upon in this MOU. It may be amended by written agreement of both parties at any time prior to its expiration or termination. The parties shall seek to resolve any dispute concerning the MOU through good faith discussions. The MOU may be terminated at any time upon sixty days' written notice by either party to the other.

VIII. Program Officers

John V. Scalera
USEPA
OPPT/CMD/TPB (TA-798)
401 M Street, SW
Washington, DC 20460

IX. ORGANIZATIONAL APPROVAL

Mark A. Greenwood, Director
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency

Environmental Protection Agency

APPROVED:

Mark A. Greenwood

Date

[ORGANIZATION'S NAME]

APPROVED:

[APPROVING OFFICIAL]

Date

APPENDIX A

EPA NATIONAL LEAD LABORATORY ACCREDITATION PROGRAM

LABORATORY QUALITY SYSTEM REQUIREMENTS

REVISION 1.0

5/14/1993

The requirements stated below must be satisfactorily met by all laboratories participating in the Environmental Protection Agency's (EPA) National Lead Laboratory Accreditation Program (NLLAP). Independent of meeting the following laboratory quality system requirements, the laboratory must also successfully participate in the Environmental Lead Laboratory Proficiency Testing (ELPAT) Program. The ELPAT Program is a cooperative effort of the American Industrial Hygiene Association (AIHA), and researchers at the Center for Disease Control and Prevention (CDC), National Institute for Occupational Safety and Health (NIOSH) and the U.S. EPA, Office of Pollution Prevention and Toxics (OPPT).

Laboratory accrediting organizations recognized by the NLLAP through a memorandum of understanding (MOU), will conduct system audits inclusive of on-site visits using as a minimum the following requirements. Laboratories which successfully perform in the ELPAT Program and pass the system audit, will be recognized by the NLLAP as capable of analyzing for lead in paint chips, dust and soil samples associated with the abatement and control of lead-based paint.

Concerning any future revisions of the NLLAP Laboratory Quality System Requirements, laboratories currently participating in the NLLAP will be given a period of six months from the posting of the revision on the Government Printing Office's Federal Bulletin Board to conform to any new requirements stated in the revision.

For further information concerning the NLLAP, please address your request in writing to:

**John Scalera (Mail Code TS-798)
U.S. Environmental Protection Agency
Office of Pollution Prevention and Toxics
401 M Street, S.W.
Washington D.C. 20460**

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LABORATORY QUALITY SYSTEM REQUIREMENTS

1. ORGANIZATION AND FUNCTION

1.1 Laboratory Facility

The organization requesting accreditation shall own a functioning laboratory operation at a fixed site or in a self-contained, mobile facility. A mobile laboratory is defined as a laboratory that moves under its own power or is conveyed on a trailer, and does not remain at a site for more than two years.

1.2 Single Site Accreditation

Accreditation shall be extended only to a single facility. Organizations desiring accreditation for multiple facilities shall submit individual and separate applications for each facility.

1.3 Lead Analysis Capability

The laboratory for which the organization is requesting accreditation shall possess an in-house lead analysis capability that constitutes an identifiable part of the overall laboratory operation.

2. QUALITY SYSTEM

All laboratories seeking accreditation shall have in place a quality system which is documented in a quality manual and related supporting documents including standard operating procedures (SOPs).

2.1 Quality System Documents

The current version of the laboratory quality manual (QM) shall be made available to the accrediting organization upon initial application and with each subsequent reaccreditation application. The QM and related documents shall reflect the implemented quality system in operation at the laboratory. The QM and related quality system documents shall include quality control (QC) requirements of the approved methods used. The QM shall include or address at least the following elements:

- þ Title Page
- þ Table of Contents
- þ Organization and Responsibility
- þ Quality Assurance Objectives and Policies
- þ Personnel Qualifications and Training
- þ Sampling Procedures (when applicable)
- þ Chain-of-Custody/Sample Receipt Procedures
- þ Reagents and Standards
- þ Equipment Calibration and Maintenance Procedures
- þ Analytical Methods
- þ Data Reduction, Validation and Reporting
- þ Internal Quality Control Procedures
- þ Performance and System Audits
- þ Corrective Action
- þ Quality Assurance Reports
- þ Documentation and Record Keeping
- þ Sample Retention and Disposal

This documented quality system manual shall be updated whenever necessary and reviewed and approved by management not less frequently than annually. The quality manual shall be accessible to all laboratory personnel.

3. FACILITIES

A laboratory shall have the space, equipment, instruments, ventilation, utility services, storage space, safety equipment, and documentation and references necessary to accomplish the analyses for lead concentrations in the matrices of concern (paint films/chips, dust and soil) as per 29 CFR 1910.1450.

Requirements for mobile laboratories shall be the same as those for fixed facilities. Utilities and services shall be available and consistent with those of fixed laboratory operations.

3.1 Sample Receipt and Storage

Appropriate area and equipment shall be provided for sample receipt, storage and processing.

3.2 Environmental Control

Temperature and humidity must be controlled to meet instrument and/or sample analysis requirements.

3.3 Mobile Laboratory Location

An historical record of mobile laboratory locations shall be maintained for at least ten years clearly indicating where the analytical work was performed.

4. PERSONNEL QUALIFICATIONS AND TRAINING

Analysts shall complete an external or internal training program for lead or applicable metals analysis prior to performing analyses on submitted samples. The criteria and training requirements for laboratory personnel shall be clearly defined, documented and maintained on file. The documentation shall include a description of the training program content, the duration of the training, qualifications of the trainer, and objective evidence that the analyst has successfully analyzed unknown reference samples of the matrices of concern within the specified acceptance criteria.

Laboratory personnel shall meet the following criteria:

4.1 Technical Manager

The individual who functions as the Technical Manager (however named) of the lead analysis laboratory shall possess a college degree in Chemistry or a related science and have at least three years nonacademic analytical chemistry laboratory experience of which at least 2 years shall be metals analysis experience. The Technical Manager shall be on-site at least 50% of the time.

4.2 Quality Manager

The individual who functions as the Quality Manager (however named) of the lead analysis laboratory shall possess a college degree in a basic or applied science and have at least one year of nonacademic analytical

chemistry experience and training in statistics. Alternatively, the individual can have four years of nonacademic analytical chemistry experience and training in statistics. The Technical Manager may also function as the Quality Manager so long as he does not act in the position as the sample analyst/technician analyzing the samples or act as the immediate supervisor of the analyst/technician involved with the analysis of the samples.

The quality manager may be employed by the laboratory on a part-time basis or as a consultant in order to meet the external monitoring function of the position.

4.3 Inorganic Chemist/Spectroscopist

This individual must have a college degree in Chemistry or related field with a minimum of 1 year nonacademic experience in metals analysis. Successful training in specific metals methods used in the laboratory shall be verified and documented using reference materials of the matrices of concern. Proficiency testing results must be documented. This category includes the following persons:

4.3.1 Inductively Coupled Plasma-Emission (ICP) Spectroscopist

Experience: 1 year

Training: Satisfactory completion of a short course on ICP. An in-house course is acceptable.

4.3.2 Flameless Atomic Absorption Spectroscopist

Experience: 1 year

Training: Satisfactory completion of a short course on Graphite Furnace Atomic Absorption (GFAA). An in-house course is acceptable.

4.3.3 Flame Atomic Absorption (FLAA) Spectroscopist

Experience: 1 year

Training: Satisfactory completion of a short course on FLAA. An in-house course is acceptable.

4.4 Analyst/Technician

Lead (Pb) analysts/technicians shall have completed a training course in metals analysis (an in-house course is acceptable) and have demonstrated ability to produce reliable results through accurate analysis of standard reference materials (SRMs), proficiency testing samples, or in-house quality control samples. Their performance

must be documented.

Junior staff (nondegreed personnel with less than 3 years relevant experience) must work under the direct supervision of the Technical Manager or under the supervision of a degreed scientist described in section 4.3 above or a sample analyst/technician who has performed successfully over a period of three years in the analysis of metals using the same technologies being applied for the analysis of lead in samples.

4.4.1 Minimum Level of Experience Required For Independent Operation

4.4.1.1 Inorganic Sample Preparation---3 months per method utilized

4.4.1.2 Routine Sample Analyst---6 months per instrument utilized

4.4.2.3 Requirements During Training

Analyst/technicians in training may work on samples submitted for Pb analysis under the NLLAP as long as the following conditions are met:

1. They have demonstrated the ability to produce reliable results through accurate analysis of SRMs, proficiency testing samples or in-house quality control samples. Their performance must be documented;
2. They have met at least 50% of the experience period required stated in sections 4.4.1.1 and 4.4.1.2 above;
3. Their immediate supervisor or instructor is physically present 70% of the time in their work area when they are preparing and/or analyzing the samples.

5. REAGENTS AND STANDARDS

Requirements for reagents and standards shall be specified in the documented quality system.

5.1 Reagent Grades Used

Reagents and standards shall be at least ACS reagent grade or of the quality specified by the analytical methods in use in the laboratory.

5.2 Reagents and Standards Tracking

Reagents and standards shall be inspected, concentrations verified (if appropriate), dated and initialed upon receipt. Standards shall have an expiration date assigned. Reagents and standards shall not be used beyond assigned expiration dates.

5.3 Documentation of Reagent and Calibration Solution Preparation

Strict control and documentation of reagent solutions and calibration standards shall be maintained. Documentation of standard and solution preparations shall include the date of preparation, concentration and/or purity of parent material concentration, assigned expiration date and preparer's initials. The concentration standards and quality control materials shall be verified upon receipt and periodically reverified.

5.4 Calibration Standards and Quality Control Materials

Purchased quality control materials and calibration standards shall be traceable to NIST standards, if such are available.

6. SAMPLE TRACKING PROCEDURES

The laboratory shall have a standard operating procedure (SOP) for sample receiving and tracking procedures. This procedure shall describe a unique laboratory identification system to identify each sample and/or batch of samples received by the laboratory. The procedure shall include documentation of the sample's condition at the time of receipt and the name of the individual receiving the sample.

6.1 Sample Tracking

A sample receipt record shall be used to record the receipt of all samples. The record shall contain at a minimum the following:

- b Unique sample identification**
- b Date received**
- b Client identification**
- b Designated sample storage area**
- b Analysis requested**
- b Comments section**

6.2 Batch/Sample Identification

If a batch identification system is used, in addition, each sample shall be identified

by a unique laboratory identifier.

6.3 Sample Rejection

Along with the SOP for sample receipt, sample rejection criteria shall be documented, as well as procedures for advising field personnel and the client of problems with samples.

6.4 Subsample Identification

An identification scheme shall be documented and utilized when applicable in order to designate sample extracts, split samples and duplicates.

7. EQUIPMENT

All equipment utilized in the preparation of samples for instrumental analysis shall be maintained and calibrated in accordance to manufacturer standards, the standards stated in "ISO/IEC Guide 25: 1990 (E)", as well as any specifications stated in the analytical methods used.

8. ANALYTICAL INSTRUMENTATION

Each instrument used in the analysis of lead shall have standard operating procedures for calibration and use readily available to the analyst. Calibration and maintenance procedures shall be specified and recorded for support equipment.

8.1 Instrument Maintenance Records

Records shall be maintained for each major instrument, including records of in-house preventive maintenance and service. Instrument calibration and maintenance procedures and the frequency of such shall be stated. Problem or service descriptions, dates and types of repair, and person performing repair shall be recorded. Instruments which are out of calibration or defective shall be taken

out of service until repaired and demonstrated to be functioning within acceptable limits. The record shall identify the instrument by make, model number, serial number, and when available, the date placed in service.

8.2 Instrument Performance Checks

Instruments shall be subject to performance checks prior to use for analysis of samples. Such checks may include evaluation of instrument sensitivity, noise levels and absorbance/emission levels versus historical values. Acceptance criteria shall be stated.

8.3 Instrument Calibration

A minimum of 3 calibration standards (except for ICP) which bracket the sample concentrations and a blank shall be analyzed to construct a calibration curve on a daily basis before the analysis of samples. Acceptance criteria shall be stated.

New curves shall be prepared whenever an out-of-control condition is indicated and after new reagents are prepared.

For ICP analyses, where possible, a minimum of a two point calibration plus a blank shall be performed each day of use before the analysis of samples. Linearity shall be confirmed by the calibration standards, their concentrations encompassing the concentration range of interest for the samples to be analyzed. Analyst using instruments with software utilizing only a single high standard for calibration, are to perform a calibration check using a reference sample with a concentration at the low end of the range of interest. In addition, an interference check standard shall be analyzed each day of use. Acceptance criteria shall be stated (see section 11).

Calibration blanks must be successfully analyzed before and periodically with the analysis of samples. The calibration blank solutions consist of the same reagents used to digest the samples. Performance criteria are stated in section 11.

8.3.1 Instrument Calibration Verification

Prior to analyzing samples, an initial calibration verification (ICV) standard must be analyzed. The source of the ICV standard must be independent from the instrument calibration samples and NIST traceable. See section 11 for performance criteria.

8.3.2 Continuing Calibration Verification

Continuing calibration verification (CCV) standards shall be analyzed in accordance to the analytical SOP. The CCV standard may be prepared from independent reference standards or from the same standards used to prepare the instrument calibration curve. Acceptance criteria shall be stated (see section 11).

9. ANALYTICAL METHODS--SAMPLE PREPARATION AND ANALYSIS

Sample preparation and analyses shall be conducted using those methods mandated by legal/regulatory requirements, recognized published methods, or methods developed and validated by the laboratory. Methods may not be used for sample analysis until competence for each particular matrix has been demonstrated by the laboratory. These methods shall be available to all analysts in the form of written standard operating procedures (SOPs). The SOP shall be dated and approved for use by the Technical Manager.

9.1 Standard Operating Procedures

All standard operating procedures shall supply information addressing the following areas:

Interferences	Instrument Calibration
Safety Considerations	Quality Control Procedures
Apparatus and Equipment	Detailed Step-by-Step Procedure
Reagents and Supplies	Sample Calculations
Sample Preservation and Storage	Method Performance (Accuracy and Precision)
Sample Preparation	

Laboratory standard operating procedures which do not address all of the areas stated above may amend their procedures through attachments in order to meet this requirement or reference their quality system documents as appropriate. All operational procedures must be available to each analyst at the laboratory work area.

9.1.1 Quality Control Specifics

The laboratory shall have quality control (QC) procedures stated in their quality system documents including their quality manual (QM) and/or in each method's standard operating procedures addressing, as appropriate, the use of:

Reagent/method blank analyses;

Replicate/duplicate sample analysis;

Spiked and blank sample analysis;

Blind samples;

Quality control samples;

Control charts or equivalent;

Calibration standards;

Reference material samples;

Internal standards.

9.2 SOP Review/Revision

The laboratory shall state in its QM or document control SOP, the process utilized in the adoption and revision of analytical procedures employed by the laboratory, including when and how the laboratory standard operating procedures manual is reviewed and/or revised.

9.3 Acceptable Methodology

Procedures published by federal agencies (EPA, NIOSH, etc.), nationally or internationally recognized technical authorities or other validated procedures may be acceptable to use once the laboratory has demonstrated adequate performance with the method for each particular matrix. Alternative procedures and/or modifications of methods may be used if they have been validated by the laboratory, meeting the minimum performance acceptance limits stated in section 11.4 of this document eighty percent of the time. The method validation procedures used must be documented. An example of a method validation procedure would be the evaluation of a minimum pool of twenty consecutively analyzed QC sample results for each type of QC sample applicable. In reviewing the performance of the laboratory control samples (LCS), for 20 consecutively analyzed LCS samples, no more than 4 of the twenty samples could demonstrate percent recoveries outside of $\pm 20\%$ acceptance limits in order for the method to be considered for potential use. Similarly, the performance of the other QC samples would also be evaluated.

9.4 Method Performance Evaluation

Linear calibration ranges (or working calibration ranges) shall be established and routinely verified for each method. Method detection limits (MDLs) shall be established and statistically verified at least annually for each method and matrix of concern (paint chips, soil and/or dust). For methods with stated MDLs, demonstration of ability to achieve such MDLs is required and must be documented. MDLs shall be determined using procedures published or recognized by federal agencies (EPA, NIOSH, etc.) or nationally or internationally acknowledged technical authorities. An example of an acceptable recommended procedure is 40 CFR 136 Appendix B.

10. DATA REDUCTION, VALIDATION AND REPORTING

Laboratories shall establish and maintain a data review process beginning at sample receipt and extending through the report process. Supervisory personnel shall review the data calculations and QC results. Deviations or deficiencies in quality shall be documented and reported to management. QC data shall be retrievable for

all analytical and/or testing results. Independent review is to be done by someone other than the analyst who generated the data prior to its release.

10.1 Data Reduction and Review Process

The data reduction and review process shall include, but not necessarily be limited to: comparison of quality control data against established acceptance limits; computation verification; transcription of data; and adherence to the procedures established in the laboratory's SOPs. The review process shall be documented.

10.2 Data Correction Process

Any corrections made to data shall be documented with a single strike out line and the analyst's initials and date. All hand written data shall be recorded using indelible ink and no correction fluid may be used on original laboratory data records.

10.3 Laboratory Test Reports

10.3.1 Final Test Reports

The actual amount of information associated with the evaluation of samples to be submitted to the client is based upon the request of the client. Independent of what information is submitted to the client, the laboratory is required to generate and keep on file a final test report in each case where the client submits a single lot of samples for analysis containing fifty or more samples. The test report shall include the following information and be maintained by the laboratory for a period of ten years:

- p Cover page information including sample preparation and analysis methods, appropriate dates, instruments, analyst identity and sign-offs by the laboratory director.**
- p Sample information including identification, blanks, QC samples, sample weights, dilution factors, and batch identification.**
- p Results of initial precision and accuracy runs.**
- p Results of calibration including sources of standards and detection limits.**

- p Results of blanks including type of blank and any corrections used.**
- p Results of calibration verification checks.**
- p Results of tests for accuracy and precision.**
- p Data reduction and reporting procedures including data calculations, outliers, and data archiving.**

Details concerning information to be included in the above categories is stated in Appendix 5 of the HUD "Lead-Based Paint: Interim Guidelines for Hazard Identification and Abatement in Public and Indian Housing" (September 1990).

In cases where the total number of samples submitted by the client in a single lot is less than fifty samples, depending upon the client's request, a test report containing the elements described above may not be required, however, the laboratory is responsible to retain the above information associated with the samples for a period of ten years, and upon request, must be able to assimilate the above information for all samples analyzed under the NLLAP.

10.3.2 Corrections

If corrections or additions to a test report are made, they shall be documented, and the report reissued as an amended report.

10.3.3 Reporting Values Below the Method Quantitation Limit

Measurement values below the method quantitation limit (MQL) shall be reported as "<" along with reference to the method quantitation limit. The reporting of zero concentration is not permitted.

10.3.4 Report Sign Off

Final reports shall be reviewed and signed by the Technical Manager or his/her designee.

11. QUALITY CONTROL PRACTICES

The laboratory quality control program shall include the continual evaluation of its performance (system process control) for each matrix which includes the determination of accuracy and precision. One possible method used for laboratory

system process control is the use of control charts to monitor the performance of a specific QC samples. Control charts must specify warning and action limits. In the absence of a statistically sufficient data base to determine the necessary frequency for QC samples, the laboratory must default to the use of a set frequency for QC samples stated in its analytical standard operating procedure. Sections 11.1 through 11.4 below state required minimum performance criteria and QC sample frequency for analytical SOPs employing AAS or ICP in the absence of QC sample frequency determinations based on the use of system process control data produced by the laboratory for the specific method utilized.

11.1 Precision and Accuracy Determinations

Accuracy studies are performed to determine how close a measurement comes to an actual or accepted reference value. Accuracy can be expressed as percent recovery and evaluated by analysis of matrix spike samples. A matrix spike is an aliquot of a sample fortified (spiked) with a known quantity of the analyte of interest and subjected to the entire analytical procedure.

Precision is evaluated by the reproducibility of analyses. Precision is commonly expressed as standard deviation or relative percent difference and can be evaluated by the analysis of replicate samples. Replicate sample analyses are one or more additional analyses on separate portions of a given sample in order to assist in the evaluation of method variance. Most commonly, two replicate analyses (defined as a duplicate analysis) are performed.

In the analysis of soil, dust (vacuum) and paint chip matrices, samples may be too small and difficult to homogenize and split to obtain samples for matrix spike evaluations or replicate analyses. For samples where such is the case, the laboratory must select alternative QC options such as the analysis of duplicate laboratory control samples per batch in order to monitor laboratory performance.

11.1.1 Paint Chip, Soil and Vacuumed Dust Samples

11.1.1.1 Accuracy Determination

Matrix spiked samples shall be analyzed with a minimum frequency of five percent (5%) of the samples for each matrix, per batch of samples (samples processed at a single time). If there are fewer than 20 samples in a batch, at least one spiked sample for each matrix, per batch shall be analyzed.

11.1.1.2 Precision Determination

Replicate (duplicate) samples shall be analyzed with a minimum frequency of five percent (5%) of samples for each matrix, per batch of samples. If there are fewer

than 20 samples in a batch, at least one sample for each matrix, per batch shall be analyzed. In the event the analyte is not detected in the sample, replicate matrix spike samples may be analyzed.

11.1.2 Dust Wipe Samples

11.1.2.1 Accuracy and Precision Determinations

When analyzing wipe samples, method spike samples shall be prepared using blank collection media with a minimum frequency of five percent (5%). If there are fewer than 20 samples per batch, at least one method spike/spike duplicate set shall be analyzed per batch. The matrix samples are to be prepared using a lead-based paint (NIST SRM traceable) applied directly to the wipe.

11.2 Method Blanks

When using methods requiring sample pretreatment not performed on calibration standards, a method blank containing all reagents and subject to all preparation steps shall be processed and analyzed along with the samples. Method blanks shall be analyzed with a minimum frequency of five percent (5%) of the samples for each matrix, per batch of samples. If there are fewer than 20 samples in a batch, at least one method blank for each matrix, per batch shall be analyzed. The use of method blanks provide a measurement of laboratory and/or reagent contamination. Method blanks shall not be used to correct sample results.

11.3 External Reference or Laboratory Control Sample Analysis

Prior to sample analysis, at least one independent lead reference or laboratory control sample (LCS) shall be analyzed with each matrix, per batch of samples with a minimum frequency of 5%. If there are fewer than 20 samples per batch, than at least 1 reference or control sample shall be analyzed per batch per matrix type. The concentration of the control sample shall be within the working range of the method and shall not require extensive pretreatment, dilution or concentration prior to analysis. Sources of these samples include but are not limited to: NIST Standard Reference Materials, proficiency testing samples from the ELPAT Program, commercially available certified reference samples, or samples prepared from different sources of analyte than calibration standards and whose concentrations were determined using definitive methods. All reference or laboratory control sample materials shall be NIST traceable.

11.4 Acceptance Limits

Acceptable performance limits for analytical instrumentation as well as each

method shall be established based upon the continuing statistical evaluation of the data generated by the analysis of quality control samples, unless specific minimum acceptance limits are established by the method. The laboratory's calculation procedures for statistically derived acceptance limits shall be documented. Some methods have listed acceptance criteria for applicable analytes based upon determinations by a single laboratory, the compilation of data from many laboratories, or limits that are assumed or expected. These limits may be too broad to define accurate acceptance criteria for routine use. These limits are best used as guidelines during the initial phases of method use and are superseded when the laboratory has collected sufficient self-generated data for proper statistical evaluation.

In the absence of sufficient data for the statistical determination of adequate QC sample frequency, the following minimum QC sample frequencies are required (where applicable) for analytical SOPs employing AAS or ICP instrumentation:

QC Sample	Frequency	Acceptance Limits
Initial Calibration Verification (ICV)	Once per run after calibration.	Within $\pm 10\%$ of known value.
Initial Calibration Blank (ICB)	Once per run at the beginning of run.	Absolute value not more than 20% of the regulatory limit or minimum level of concern.
Continuing Calibration Verification (CCV)	Before and at the end of a sample run as well as every 10 samples.	Within $\pm 10\%$ of known value for ICP or FAAS; Within $\pm 20\%$ for GFAA.
Interference Check Sample (ICS)	Beginning & end of each run or twice every 8 hours.	Within 20% of known value.
Continuing Calibration Blank (CCB)	After each ICS and CCV.	Absolute value not more than 20% of the regulatory limit or minimum level of concern.
Laboratory Control Sample (LCS)	1 per 20 samples or batch (5%).	Within $\pm 20\%$ of known value.

Matrix Spike	1 per 20 samples or batch (5%).	Within $\pm 25\%$ of known value.
Duplicate Sample	1 per 20 samples or batch (5%).	Within $\pm 25\%$ RPD.
Method Blank	1 per 20 samples or batch (5%).	Absolute value not more than 20% of the regulatory limit or minimum level of concern.

11.5 Control Charts

Control charts or a quality control data base shall be used to record quality control data and track laboratory performance with the associated acceptance limits for each matrix and to evaluate instrument performance.

11.6 Contamination Control

11.6.1 Laboratory Dust Wipe Checks

Wipe sampling and analysis shall be conducted at least quarterly to determine surface concentration levels of lead in the laboratory. The laboratory systems documents shall specify the maximum allowable concentration of lead for sample preparation and analysis areas associated with the lead analysis. Sample preparation and analysis is not to proceed until surface contamination is within the specified maximum allowable concentration stated in the laboratory's quality system documents.

11.6.2 Labware Cleaning

Cleaning procedures for labware shall be specified by the laboratory in a written SOP. The procedure must include a periodic monitoring of lead concentrations in cleaning baths, where applicable, or the monitoring of glassware contamination during the analysis of reagent or other blanks. The monitoring frequency must be at least once a month.

11.6.3 Dust Wipes

Where the laboratory is responsible for taking dust sample wipes in the field, the laboratory must evaluate blank wipes representative of the lots to be used in the field for lead contamination analysis prior to field sampling.

11.7 System Audits

Internal quality assurance audits shall be conducted at least annually. The audit results must be documented and available for review by the accrediting organization.

11.8 Corrective Action

If the reported values of QC samples fall outside of the acceptance limits stated in the method, samples associated with the batch are to be reanalyzed including a new set of QC samples; no sample values are to be reported unless the QC samples are within the acceptance limits.

Laboratories shall document, investigate and take corrective action for all episodes where the QC data shows an out-of-control situation. No data shall be reported until the cause of the problem is determined and corrected, or the laboratory demonstrates the cause was a random event and no longer affects data. The laboratory shall keep records of all out-of-control events, the determined cause(s) and corrective actions taken. Laboratories shall respond to client quality

complaints and maintain records of corrective action.

12. DOCUMENTATION AND RECORD KEEPING

The document and record retention policies of the laboratory shall be stated.

12.1 Record Retention Period

The policies shall include the manner and duration of record retention. All laboratory records shall be maintained for a period of at least ten (10) years. In instances where the laboratory is going out of business, clients of Pb analyses done under the NLLAP, are to be notified 60 days in advance of the closure of the laboratory. All final test reports generated by the laboratory as required in section 10.3.1 of this document are to be submitted to the clients if not previously done.

12.2 Hard Copies

Computer records are satisfactory without hard copy files, provided hard copies can be generated as needed. The computer programs must be validated before they are used and verified on a regular basis through spot checks of computer calculations. Computer file back up procedures are required.

13. SAMPLE RETENTION AND DISPOSAL

The sample retention and disposal policies of the laboratory shall be stated.

13.1 Sample Retention

The policies shall include documenting the manner and duration of sample retention.

13.2 Sample Disposal

Laboratories shall comply with all applicable federal, state and local regulations regarding environmental contamination and waste disposal.

APPENDIX A1

ACRONYMS AND GLOSSARY OF TERMS ASSOCIATED WITH THE NLLAP

ACRONYMS

AA	Atomic Absorption
A2LA	American Association for Laboratory Accreditation
ACIL	American Council of Independent Laboratories
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
AOAC	Association of Official Analytical Chemists
APHA	American Public Health Association
ASTM	American Society for Testing and Materials
ASQC	American Society for Quality Control
ASTPHLD	Association of State and Territorial Public Health Laboratory Directors
AWWA	American Water Works Association
CCB	Continuing Calibration Blank
CCV	Continuing Calibration Verification
CERCLA	Comprehensive Environmental Responsibility, Compensation and Liability Act
CDC	Centers for Disease Control
CMD	Chemical Management Division
CNAEL	Committee on National Accreditation of Environmental Laboratories
CRADA	Cooperative Research and Development Agreement
CLP	Contract Laboratory Program
CRM	Certified Reference Material
EDL	Estimated Detection Limit
ELLAC	Environmental Lead Laboratory Accreditation Committee (AIHA)
ELPAT	Environmental Lead Proficiency Analytical Testing (AIHA/NIOSH)
EMPC	Estimated Maximum (Protocol) Concentration
FLAA	Direct Flame Aspiration Atomic Absorption Spectrometry
GFAA	Graphite Furnace Atomic Absorption Spectrometry
GLP	Good Laboratory Practices Standards (TSCA)
ICB	Initial Calibration Blank
ICP-AES	Inductively Coupled Plasma Emission Spectrometry
ICP-MS	Inductively Coupled Plasma-Mass Spectrometry
ICV	Initial Calibration Verification
ICS	Interference Check Standard
IDL	Instrument Detection Limit
IMVL	Interlaboratory Method Validation Study
ISO	International Organization for Standardization
LCS	Laboratory Control Sample
LOQ	Limit of Quantitation
LSA	Laboratory Systems Audit
MCL	Maximum Contaminant Level
MDL	Method Detection Limit
MOU	Memorandum of Understanding
MRI	Midwest Research Institute
NATA	National Association of Testing Authorities (Australia)
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
NLLAP	National Lead Laboratory Accreditation Program
NTIS	National Technical Information Service
NVLAP	National Voluntary Laboratory Accreditation Program
OSW	Office of Solid Waste (U.S. EPA)
PE	Performance Evaluation
PM	Preventive Maintenance
PT	Proficiency Testing
PQL	Practical Quantitation Limit
QA	Quality Assurance
QAMS	Quality Assurance Management Staff
QAPjP	Quality Assurance Project Plan
QAPP	Quality Assurance Program Plan
QC	Quality Control
QM	Quality Manual
RCRA	Resource Conservation and Recovery Act
RE	Relative Error
RPD	Relative Percent Difference
SAP	Sample Analysis Plan
SARA	Superfund Amendments and Re-authorizations Act of 1986
SOP	Standard Operating Procedure
SRM	Standard Reference Material Produced by NIST
TCLP	Toxicity Characteristic Leaching Procedure

TPB	Technical Programs Branch
TQM	Total Quality Management
TSCA	Toxic Substances Control Act
XRF	X-Ray Fluorescence
WAL	Work Assignment Leader
WAM	Work Assignment Manager
WPCF	Water Pollution Control Federation

GLOSSARY

Accreditation:	A formal recognition that an organization (e.g., laboratory) is competent to carry out specific tasks or specific types of tests. See also Certification .
Accredited laboratory:	A laboratory that has been evaluated and given approval to perform a specified measurement or task, usually for a specific property or analyte and for a specified period of time.
Acceptance limits:	Data quality limits specified by the National Lead Laboratory Accreditation Program for analytical method performance.
Accuracy:	The degree of agreement between an observed value and an accepted reference value. Accuracy includes a combination of random error (precision) and systematic error (bias) components which are due to sampling and analytical operations; a data quality indicator. See Precision and Bias .
Aliquot:	See Subsample
Analytical blank:	See Digestion blank .
Batch:	A quantity of material produced or processed in one operation, considered to be a uniform, discrete unit.
Bias:	The systematic error manifested as a consistent positive or negative deviation from the known true value.
Blind sample:	A subsample submitted for analysis with a composition and identity known to the submitter but unknown to the analyst and used to test the analyst's or laboratory's proficiency in the execution of the measurement process.
Calibrate:	To determine, by measurement or comparison with a standard, the correct value of each scale reading on a meter or other device, or the correct value for each setting of a control knob. The levels of the calibration standards should bracket the range of planned measurements. See Calibration curve .
Calibration blank:	See Initial calibration blank .
Calibration-check:	See Calibration verification .
Calibration-check standard:	See Calibration verification .
Calibration curve:	The graphical relationship between the known values for a series of calibration standards and instrument responses.
Calibration drift:	The difference between the instrument response and a reference value after a period of operation without recalibration. See Continuing calibration verification .
Calibration standard:	A substance or reference material used to calibrate an instrument.
Calibration solution:	See Calibration standard .
Calibration verification:	See Initial or continuing calibration verification .
Certification:	The process of testing and evaluation against specifications designed to document, verify, and recognize the competence of a person, organization, or other entity to perform a function or service usually for a specified time. See also Accreditation .
Certified Reference Material (CRM):	A reference material that has one or more of its property values established by a technically valid procedure and is accompanied by or traceable to a certificate or other documentation issued by a certifying body. See Certification and Reference material .
Chain of custody:	An unbroken trail of accountability that insures the physical security of samples, data, and records.
Check sample:	An uncontaminated sample matrix spiked with known amounts of analytes, usually from the same source as the calibration standards. It is generally used to establish the stability of the analytical system, but may also be used to assess the performance of all or a portion of the measurement system. See also Quality control sample .

Continuing Calibration Blank (CCB)	A standard solution which has no analyte and is used to verify blank response and freedom from carryover. The CCB should be analyzed after the CCV and after the Interference Check Standard (ICS).
Continuing Calibration Verification (CCV)	A standard solution (or set of solutions) used to verify freedom of excessive instrumental drift. The concentration to be near mid-range of linear curve. The CCV should be matrix matched to acid content present in sample digestates. The CCV should be analyzed before and after all sample digestes.
Control chart:	A graph of some measurement plotted over time or sequence of sampling, together with control limit(s) and, usually, a central line and warning limit(s).
Control sample:	See Laboratory control sample .
Corrective action:	Action taken to correct a deficiency noted in a technical systems audit. See Deficiency and Technical systems audit .
Deficiency:	A failure to fully comply with the requirements of the NLLAP program usually noted during a technical systems audit. See NLLAP and Technical systems audit .
Digestion blank:	A mixture of all reagents used for the digestion of paint, soil, or dust matrices but without the matrix. This blank, is carried through all steps of the analysis starting with the digestion step. This blank evaluates the process for contamination from the laboratory.
Duplicate analyses or measurements:	The analyses or measurements of the variable of interest performed identically on two subsamples of the same sample. The results from duplicate analyses are used to evaluate analytical or measurement precision but not the precision of sampling, preservation, or storage internal to the laboratory.
Duplicate samples:	Two samples taken from and representative of the same population and carried through all steps of the sampling and analytical procedures in an identical manner. Duplicate samples are used to assess variance of the total method including sampling and analysis.
External quality control:	Activities that are routinely initiated and performed by persons outside of normal operations to assess the capability and performance of a measurement process.
Field blank:	A clean sample of matrix (e.g., paint, soil, dust, wipe) carried to the sampling site, exposed to the sampling conditions (e.g., bottle caps removed), returned to the laboratory, treated as an environmental sample, and carried through all steps of the analysis. For example, clean quartz sand, non-Pb containing paint, or a clean wipe could be used as a field blank. The field blank, which should be treated just like the sample, evaluates possible site contamination sources such as airborne contaminants.
Initial calibration blank (ICB):	A standard solution that contains no analyte and is used for initial calibration and zeroing instrument response. The ICB must be matrix matched to acid content present in sample digestates. The ICB should be measured during calibration and after calibration.
Initial calibration verification (ICV):	A standard solution (or set of solutions) used to verify calibration standard levels. Concentration of analyte to be near mid-range of linear curve which is made from a stock solution having a different manufacturer or manufacturer lot identification than the calibration standards. The ICV must be matrix matched to acid content present in sample digestates. The ICV should be measured after calibration and before measuring any sample digestates.
Instrument maintenance log:	A chronological record of preventive and emergency maintenance performed on an analytical instrument. The logs include record of calls, service technician summaries, records of calibration etc.
Interference check standard (ICS):	A standard solution (or set of solutions) used for ICP-AES to verify accurate analyte response in the presence of possible spectral interferences from other analytes present in samples. The concentration of analyte to be less than 25% of the highest calibration standard, concentration of interferant will be 200 µg/ml of Al, Ca, Fe, and Mg. The ICS must be matrix matched to acid content present in sample digestates.
Internal quality control:	See Intralaboratory quality control .
Internal standard:	A standard added to a test portion of a sample in a known amount and carried through the entire demonstration procedure as a reference for calibration and controlling the precision and bias of the applied analytical method.
Intralaboratory precision:	A measure of the method/sample specific analytical variation within a laboratory, usually given as the standard deviation estimated from the results of duplicate/replicate analyses.
Intralaboratory quality control:	The routine activities and checks, such as periodic calibrations, duplicate analyses, and spiked samples, that are included in normal internal procedures to control the accuracy and precision of measurements.
Laboratory blank:	See Digestion blank .

Laboratory control sample (LCS):	A matrix-based reference material with an established concentration obtained from a source independent of the instrument calibration and traceable to NIST or other reference materials. The LCS is carried through the entire procedure from digestion through analysis as a field sample. The purpose of the LCS is to evaluate bias of the method.
Laboratory systems audit:	See <u>Technical systems audit</u> .
Lot:	A set of samples submitted together for laboratory analysis which can be treated as one or more batches.
Matrix blank:	A sample of the matrix (paint chips, soil, dust) but without the analyte (Pb). This sample goes through the complete analysis including digestion.
Method blank:	See <u>Digestion blank</u> .
Method performance:	A general term used to document the characteristics of a method. These characteristics usually include method detection limits, linearity, precision, accuracy and bias.
Method detection limit (MDL):	The minimum concentration of an analyte that, in a given matrix and with a specific method, has a 99% probability of being identified, qualitatively or quantitatively measured, and reported to be greater than zero.
Mobile laboratory:	A mobile laboratory is a self-contained, mobile facility that moves under its own power or is conveyed on a trailer, and does not remain at a site for more than two years.
NLLAP requirements:	Requirements specified by the EPA National Lead Laboratory Accreditation Program (NLLAP) in order to be accredited for lead analysis in paint, soil and dust matrices by an EPA-recognized laboratory accreditation organization.
Precision:	The degree to which a set of observations or measurements of the same property, usually obtained under similar conditions, conform to themselves; a data quality indicator. Precision is usually expressed as standard deviation, variance, or range, in either absolute or relative terms.
Primary standard:	A substance or device with a property or value that is unquestionably accepted (within specified limits) in establishing the value of the same or related property of another substance or device.
Proficiency testing:	A systematic program in which one or more standardized samples is analyzed by one or more laboratories to determine the capability of each participant.
Quality assurance (QA):	An integrated system of activities involving planning, quality control, quality assessment, reporting, and quality improvement to ensure that a product or service meets defined standards of quality within a stated level of confidence.
Quality assurance program:	See <u>Quality assurance</u> .
Quality assurance coordinator:	See <u>Quality manager</u> .
Quality control (QC):	The overall system of technical activities whose purpose is to measure and control the quality of a product or service so that it meets the needs of users. The aim is to provide quality that is satisfactory, adequate, dependable, and economical.
Quality manager:	The manager of the quality system. The Quality Manager is independent of the analyst and reports directly to management.
Quantitation Limits:	The maximum or minimum levels or quantities of a target analyte that can be quantified with the certainty required by the data user.
Reagent blank:	See <u>Digestion blank</u> .
Reference material:	A material or substance, one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or assigning values to materials.
Reference standard:	See <u>Calibration standard</u> .
Relative percent difference:	A term defined as

$$\text{RPD} = \frac{R_1 - R_2}{\bar{R}} \times 100$$

where $|R_1 - R_2|$ represents the absolute difference in two values and \bar{R} represents the average of the two values.

Replicate analysis or measurements:	The analysis or measurement of the variable of interest performed identically on two or more subsamples of the same sample within a short time interval. See Duplicate analysis or measurement .
Replicate sample:	Two or more samples representing the same population characteristic, time, and place, which are independently carried through all steps of the sampling and measurement process in an identical manner. Replicate samples are used to assess total (sampling and analysis) method variance. Often incorrectly used in place of the term "replicate analysis." See Duplicate samples and Replicate analysis .
Report sign-off:	The Technical Manager or designee authorized to review and sign analysis reports.
Reproducibility:	The extent to which a method, test or experiment yields the same or similar results when performed on subsamples of the same sample by different analysts or laboratories.
Rinseate blank:	A sample of a "used" cleaning fluid rinse solution, also called an equipment blank. Rinseate blank examples include a final rinse of the device used to collect soil or vacuumed dust or to clean the scoop used to collect soil or vacuumed dust. The rinseate blank is used in rinsing collection media and equipment prior to use to monitor possible cross contamination. The rinseate blank goes through the complete analysis, including the digestion.
Run:	A set of consecutive sample measurements.
Sample log:	The document where sample identification, condition, etc is noted when samples arrive at the laboratory. The log is part of the sample tracking system. See Sample tracking .
Sample tracking:	A system of following a sample from receipt at the laboratory, through sample processing and analysis, and to final reporting. The system includes unique numbering or bar coding labels and the use of a sample log.
Secondary standard:	A standard whose value is based upon comparison with a primary standard.
Site blank:	See Field blank .
Site visit:	An on-site visit to a laboratory for the purpose of conducting a technical systems audit.
Site visitor:	A person who conducts technical system audits. The terms site visitor, auditor and assessor are often used interchangeably. See Technical systems audit .
Spiked matrix:	See Spiked sample .
Spiked reagent blank:	A specified amount of reagent blank fortified with a known mass of the target analyte, usually used to determine the recovery efficiency of the method.
Spiked sample:	A sample prepared by adding a known mass of target analyte to a specified amount of matrix sample for which an independent estimate of target analyte concentration is available. Spiked samples are used, for example, to determine the effect of the matrix on a method's recovery efficiency.
Split samples:	Two or more representative portions taken from a sample or subsample and analyzed by different analysts or laboratories. Split samples are used to replicate the measurement of the variable(s) of interest.
Standard addition:	The procedure of adding known increments of the analyte of interest to a sample to cause increases in detection response. The level of the analyte of interest present in the original sample is subsequently established by extrapolation of the plotted responses.
Standard operating procedure (SOP):	A written document that details the method of an operation, analysis, or action whose techniques and procedures are thoroughly prescribed and which is accepted as the method for performing certain routine or repetitive tasks.
Standard reference material (SRM):	A certified reference material produced by the U.S. National Institute of Standards and Technology and characterized for absolute content independent of analytical method.
Standardization:	The process of establishing the quantitative relationship between a known mass of target material (e.g., concentration) and the response variable (e.g., the measurement system or instrument response). See Calibrate and Calibration curve .

Stock solution:	A concentrated solution of analyte(s) or reagent(s) prepared and verified by prescribed procedure(s), and used for preparing working standards or standard solutions.
Stratification:	The division of a target population into subsets or strata which are internally more homogeneous with respect to the characteristic to be studied than the population as a whole.
Subsample:	A representative portion of a sample. A subsample may be taken from any laboratory or a field sample.
Substrate:	This term has a very specialized use in the Pb-abatement area. It refers specifically to the material to which paint is attached, such as wallboard, concrete, wood, steel, etc.
Systems audit:	See <u>Technical systems audit</u> .
Technical systems audit:	A thorough systematic on-site, qualitative review of facilities, equipment, personnel, training, procedures, record keeping, data validation, data management, and reporting aspects of a total measurement system.
Trip blank:	A clean sample, including collection media, that is carried to the sampling site and transported back to the laboratory for analysis without being opened . This blank is analyzed as a regular sample through all steps. The trip blank evaluates the integrity of the sample container.
Validation:	The process of substantiating specified performance criteria.
Working standard:	See <u>Secondary standard</u> .